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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,965	12/21/2000	Earl Hubbell	3373.1	8500

7590 01/08/2004

Chief IP Counsel - Legal Dept.  
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EXAMINER

ZEMAN, MARY K

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/745,965

Applicant(s)

HUBBELL, EARL

Examiner

Mary K Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-11,13-20 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,13-20 and 22-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 Oct 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 2, 4-11, 13-20 and 22-27 are pending.

Applicant's arguments filed 10/28/03 have been fully considered but they are not completely persuasive. Any rejection not repeated herein has been withdrawn.

The amendments to the specification have been entered. Claims 3, 12 and 21 have been canceled.

Claims 1, 2, 4-11, 13-20 and 22-27 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that all of the methods required to perform the claims are well known within the art and can be practiced without undue experimentation. Applicant asserts that ample support is present in the specification for the scope of the claims, and that specific examples are provided in the specification of the claimed methods. These arguments are not commensurate in scope with the claims. The examples pointed to in the specification comprise steps and require information not provided or referred to in the claims as written.

The claims are drawn to methods of selecting probes against a target. The method comprises inputting quality scores for a plurality of probes and selecting probes based upon a maximum aggregate adjusted quality score. For the reasons set forth below, one of skill in the art would have to perform undue experimentation to practice the method of the claims.

In these claims, there is no indication that any of the probes are related to the target sequence in any way. There is no discrete comparison step, or step that relates the two sequences. The specification at page 21 indicates that a quality predictor to relate the target sequence to the potential probes is required, however, this is not set forth in the claims. At page 22, clearly both the quality predictor and a bias score predictor are required. No such functions are set forth in the claims. At pages 23-24, an additional step of checking for cross hybridization is required. This is not set forth in the claims. Tables 4-8 set forth all the information required, and steps required to practice the claimed methods- yet many of this information and the required steps are missing from the claims. As such, one of skill in the art would not be able to

practice the methods as claimed. Without these steps, one must already have in hand the “quality score” for a plurality of probes. The specification sets forth a method for predicting a quality score at pages 21-24. This is not how to obtain an *actual* quality score for any particular probe, but merely a *predicted* score. There is no teaching as to how to obtain actual quality scores other than the predicted scores. The claims do not require or set forth the steps for obtaining the predicted quality score, and the specification fails to set forth other methods to perform this step. As such one of skill in the art would need to determine how to do this critical step without guidance from the specification, which represents undue experimentation.

Applicant further argues that the application of art to the claims which also use a type of quality score is proof that obtaining such scores is fully supported, however, it is entirely unclear if these are the same quality scores that can be used in the claimed methods, and Applicant points out that the methods of that art are totally different than the invention. As such, the status of Mei et al as enabling technology is unclear.

The claims further lack steps which set forth how the actual or predicted quality scores are used to obtain the “maximum aggregate adjusted quality score.” How is this new score obtained and how is the originally input data manipulated to obtain that score? Applicant simply asserts that the step is enabled by the specification, without evidence thereto, and without amendment to the claim to clarify or set forth a clear indication of what is to be done. In the claim, no relationship to any target sequence is set forth. No specific active method steps are recited such that the preamble of the claim can be met by the method steps. How is the “adjusted score” based upon other data? The specification sets forth only a single method for adjusting scores and one of skill in the art would not be able to easily determine what other ways to base such an adjustment without undue experimentation.

In the claims, the limitation of “performing dynamic programming optimization” fails to remedy the preceding problems. On what is this to be done? To what end? Applicant argues that methods of dynamic programming are well known. The type of programming is not the issue. The issue is how to apply the concepts of dynamic programming to the specifically input data to obtain the desired results. The claims do not set forth any such method. The specification sets forth a single method comprising this process. The 5 steps at pages 30-31 appear to be required, but are not set forth in the claims. How this is otherwise to be implemented is unclear. How

would one of skill in the art be able to perform this step within the claimed methods and systems?

As such, one of skill in the art would have to provide inventive insight and perform undue experimentation to perform the methods of the claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. In January, after the move to the new facilities, the phone number will be: (571) 272-0723.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. In January, after the move to the new facilities, the phone number will be: (571) 272-0722.

The Official fax number for this Art Unit is: (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz  
12/30/03

  
MARY K. ZEMAN  
PRIMARY EXAMINER  
